510K(k) SUMMARY

SUBMITTER:	Specialities Remeex International, s.l. 55 Trende Baix Terrassa Barcelona, Spain 08223
DATE PREPARED:	September 10th 2002
DEVICE NAME:	MALE REMEEX SYSTEM
CLASSIFICATION NAMES:	Mesh, Surgical, Polymeric
PREDICATE DEVICE:	REMEEX SYSTEM

NOV - 2 2006

Device Description:

The MALE REMEEX SYSTEM (EXternal MEchanical REgulation) is included in the sling techniques for the treatment of urinary incontinence. This system is comprised of a pubourethral sling that permits the patient continence level regulation. This system use a sling, placed under the urethra that can be regulated at any time to get the most adequate bladder neck angle for a particular patient. The sling is connected by traction threads to the prosthesis. The prosthesis is situated over the fascia of the abdominal rectus muscle and is a mechanism that permits the regulation of the sling level.

Predicate Devices:

There has been a device previously cleared by the FDA in the following 510(K) Notification indicated as a pubourethral sling for the treatment of urinary incontinence:

Device	510(k) Document Number	Date Cleared	Indications
REMEEX SYSTEM	K033310	1/15/2004	Urinary Incontinence

Technologically, both the proposed and predicate devices are the same (i.e. both are meshes that provide pubourethral support) and are indicated for the treatment of urinary incontinence. Additionally, both devices utilize accessories for us in the surgical procedure.

Intended Use:

REMEEX SYSTEM Indications:

The Male Remeex System is intended to be used as a pubourethral sling for treatment of male stress urinary incontinence.

Technological Characteristics:

Technologically, both the new device and the predicate device are the same (i.e. both are meshes that provide pubourethral support). Additionally, both devices utilize accessories for use in the surgical procedure. Any differences between the two devices do not raise new questions of safety and effectiveness

Performance Data:

Results of in vitro and clinical evaluations were used to show that the Male Remeex System functioned as clinically intended. Sufficient data has been gathered from testing to assess that the Remeex System performs as intended

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the proposed device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Specialties Remneex International S.L.
% International Medical Products, Corp.
Mr. Jeffrey R. Shideman
President
7307 Glouchester Drive
EDINA MN 55435

OCT 12 2012

Re: K062341
Trade/Device Name: MALE REMEEX SYSTEM
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTM
Dated: October 6, 2006
Received: October 13, 2006

Dear Mr. Shideman:

This letter corrects our substantially equivalent letter of November 2, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

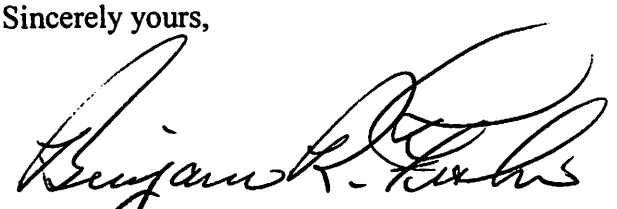
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062341

Device Name: MALE REMEEX SYSTEM

Indications for Use:

The Male Remeex System is intended to be used as a pubourethral sling for the treatment of male stress urinary incontinence

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062341